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|--|-------------|----------------------|---------------------|------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/898,751   | 07/02/2001  | Wei Wang             | DX0882XK            | 7429             |
| 7590   | 10/02/2003  |                      | EXAMINER            |                  |
| DNAX Research Institute<br>901 California Avenue<br>Palo Alto, CA 94304-1104 |             |                      | BUNNER, BRIDGET E   |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1647                |                  |

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                        |                                      |                         |
|------------------------|--------------------------------------|-------------------------|
| <b>Advisory Action</b> | <b>Application No.</b>               | <b>Applicant(s)</b>     |
|                        | 09/898,751                           | WANG ET AL.             |
|                        | <b>Examiner</b><br>Bridget E. Bunner | <b>Art Unit</b><br>1647 |

*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--*

THE REPLY FILED 20 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a)  The period for reply expires 3 months from the mailing date of the final rejection.  
 b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
 ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.  The proposed amendment(s) will not be entered because:

- (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
- (b)  they raise the issue of new matter (see Note below);
- (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See Continuation Sheet.*

3.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

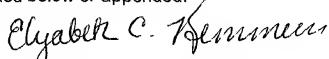
4.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.

6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.  For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_. 

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,3,4,22 and 24-33.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8.  The proposed drawing correction filed on \_\_\_\_\_ is a) approved or b) disapproved by the Examiner.

9.  Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.

10.  Other: \_\_\_\_\_

Continuation of 2. NOTE: Continuation of 2. NOTE: The recitation of "an inflammatory skin disorder" in claims 22 and 27-35 would raise new issues under 35 U.S.C. § 112, first paragraph (new matter). The specification as originally filed does not provide adequate written description for "an inflammatory skin disorder" or that an inflammatory skin disorder is wound healing, cancer, carcinoma, or infection. It is not expressly asserted, nor does it flow naturally from the specification. Additionally, even if support for this proposed phrase can be found in the specification, it may raise new issues under 35 U.S.C. § 112, second paragraph. For example, it is not clear how cancer is an inflammatory skin disorder.

If the amendment of 20 August 2003 had been entered, the rejection of claims 1, 3-4, 24-25, and 36-40 under 35 U.S.C. § 112, first paragraph would have been withdrawn in view of Applicant's persuasive arguments.

If the amendment of 20 August 2003 had been entered, the rejection of claims 22, 27-35 under 35 U.S.C. § 112 first paragraph would have been maintained. The specification while being enabling for a method of treating a patient suffering from contact allergen-induced skin inflammation or allergic-contact dermatitis comprising administering an effective amount of an antibody against cutaneous-T-cell attracting chemokine (CTACK), does not reasonably provide enablement for a method of treating a patient suffering from a skin disorder comprising administering an effective amount of an antibody against cutaneous-T-cell-attracting chemokine (CTACK). Applicant asserts that CTACK is specifically expressed in skin and selectively chemoattracts CLA+ skin-homing T cell. Applicant contends that the specification describes the treatment of an inflammatory skin disorder by administering an antibody against CTACK. Applicant argues that distribution analysis show that CTACK is expressed by keratinocytes and upregulated by pro-inflammatory cytokines (pg 65-68). Applicant indicates that CTACK expression is suppressed after treatment of clobetasol propionate, a therapeutic for inflammatory skin disease and that all the skin disorders claimed involve inflammation. Applicant states that a nexus between CTACK and inflammation has been demonstrated. Applicant's arguments have been fully considered but are no found to be persuasive. Although the specification may provide guidance as to what skin disorders should be treated by CTACK or anti-CTACK antibodies (pg 10-11), this is not adequate guidance, but is merely an invitation for the artisan to use the current invention as a starting point for further experimentation. Furthermore, although Applicant indicates that CTACK plays a role in the pathogenesis of inflammatory and autoimmune diseases, including rheumatoid arthritis, Crohn's disease, and psoriasis, the specification does not disclose that CTACK is specifically involved in these diseases and others (such as carcinoma and wound healing). Undue experimentation would be required of the skilled artisan to identify individuals with such a disease and determine the role or expression of CTACK in the pathogenesis of these diseases. Such information is necessary, especially in the determination of the optimal quantity, duration, and type of administration of anti-CTACK antibodies. Additionally, the various diseases and disorders disclosed in the specification at pg 10-11 and mentioned above, have different pathophysiologies. One skilled in the art would not be able to predict from the allergen contact experiments of the instant specification that anti-CTACK antibodies would be able to treat all possible skin disorders, such as cancer or psoriasis, or inflammatory skin disorders which have different pathophysiologies.



ELIZABETH C. KEMMERER  
PRIMARY EXAMINER